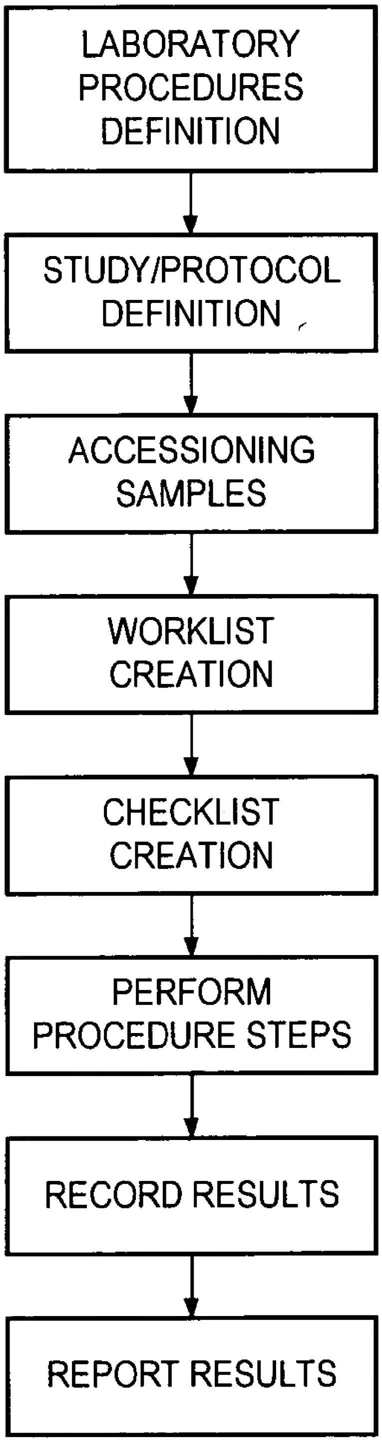
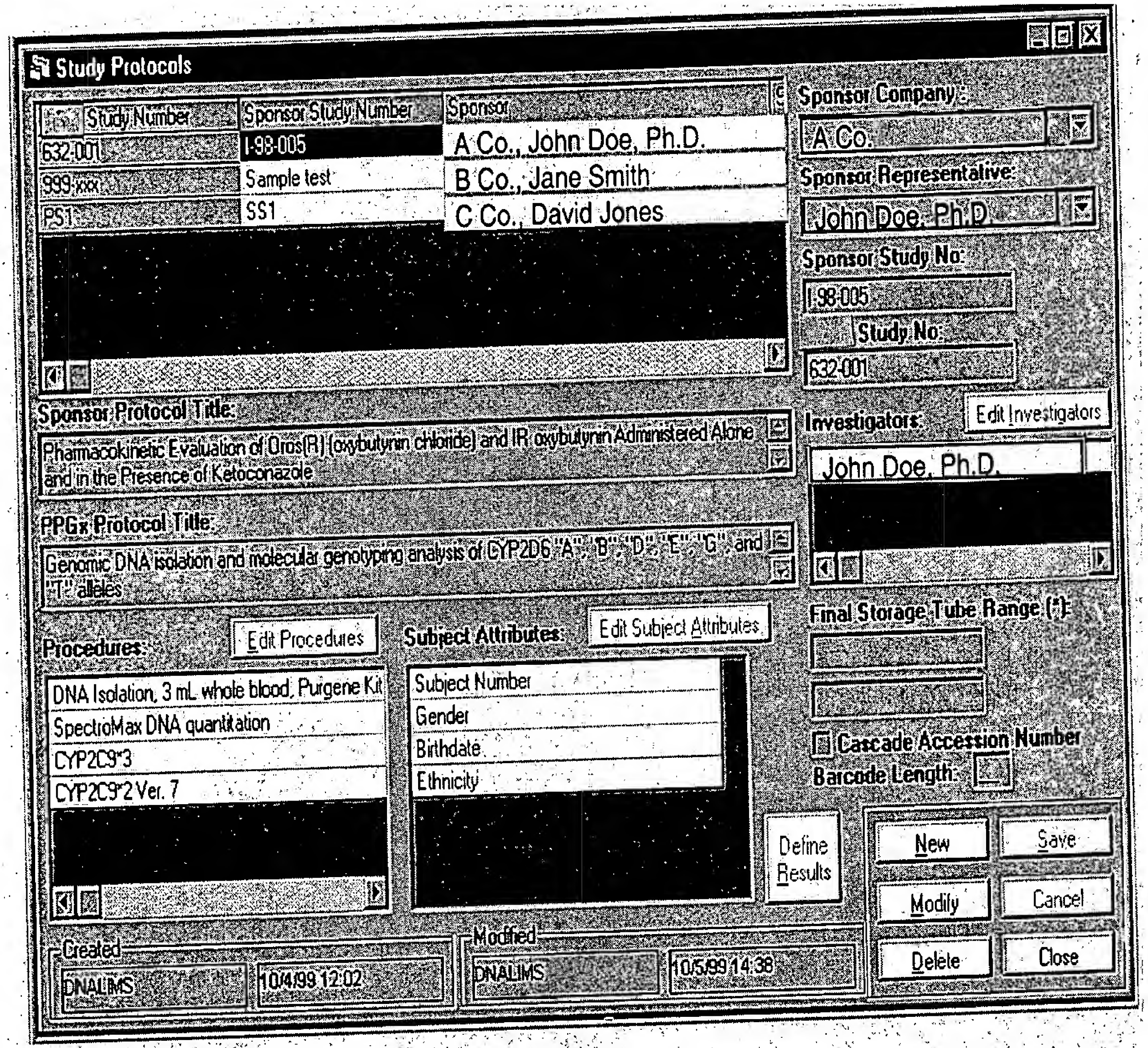

LABORATORY PROCEDURES DEFINITION
STUDY/PROTOCOL DEFINITION
ACCESSIONING SAMPLES
WORKLIST CREATION
CHECKLIST CREATION
PERFORM PROCEDURE STEPS
RECORD RESULTS
REPORT RESULTS

FIG. 1

Study Setup

Clinical Study Definition

- Describes Sponsors & Investigators
- Declares Subject Attributes to Capture
- Associates Specific Lab Procedures with a Clinical Study
- Defines Genotype Results to Report



Study Number	Sponsor Study Number	Sponsor
632-001	I-98-005	A Co., John Doe, Ph.D.
999-xxx	Sample test	B Co., Jane Smith
PS1	SS1	C Co., David Jones

Sponsor Company: A Co.

Sponsor Representative: John Doe, Ph.D.

Sponsor Study No: I-98-005

Study No: 632-001

Sponsor Protocol Title: Pharmacokinetic Evaluation of Oros(R) (oxybutynin chloride) and IR oxybutynin Administered Alone and in the Presence of Ketoconazole

Investigators: John Doe, Ph.D.

PPGx Protocol Title: Genomic DNA isolation and molecular genotyping analysis of CYP2D6 "A", "B", "D", "E", "G", and "T" alleles

Final Storage Tube Range (*):

☐ Cascade Accession Number

Barcode Length:

Procedures:

- DNA Isolation, 3 mL whole blood, Purgene Kit
- SpectroMax DNA quantitation
- CYP2C9*3
- CYP2C9*2 Ver. 7

Subject Attributes:

- Subject Number
- Gender
- Birthdate
- Ethnicity

Created: DNALIMS 10/4/99 12:02

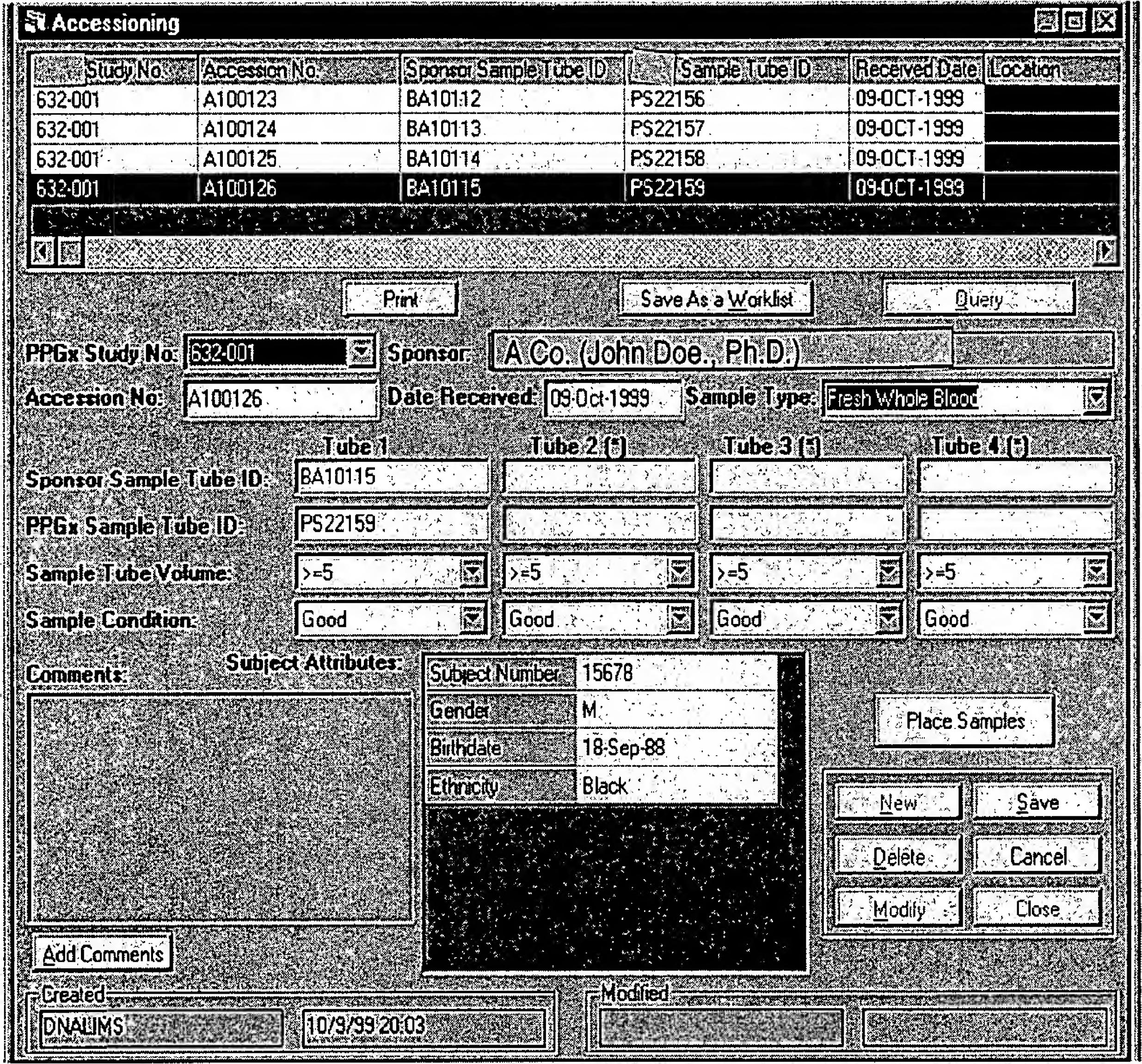
Modified: DNALIMS 10/5/99 14:38

Fig. 2

Accessioning

Clinical Sample Registration

- Provides Validation Checks for Accession & Tube ID's
- Accommodates Multiple Sample Tubes
- Enforces Controlled Subject Attribute Terms
- Supports Sample Worklist Workflow



Study No.	Accession No.	Sponsor Sample Tube ID	Sample Tube ID	Received Date	Location
632-001	A100123	BA10112	PS22156	09-OCT-1999	
632-001	A100124	BA10113	PS22157	09-OCT-1999	
632-001	A100125	BA10114	PS22158	09-OCT-1999	
632-001	A100126	BA10115	PS22159	09-OCT-1999	

PPGx Study No: 632-001 Sponsor: A Co. (John Doe., Ph.D.)

Accession No: A100126 Date Received: 09-Oct-1999 Sample Type: Fresh Whole Blood

	Tube 1	Tube 2 (*)	Tube 3 (*)	Tube 4 (*)
Sponsor Sample Tube ID:	BA10115			
PPGx Sample Tube ID:	PS22159			
Sample Tube Volume:	>=5	>=5	>=5	>=5
Sample Condition:	Good	Good	Good	Good

Comments:

Subject Attributes:

Subject Number	15678
Gender	M
Birthdate	18-Sep-88
Ethnicity	Black

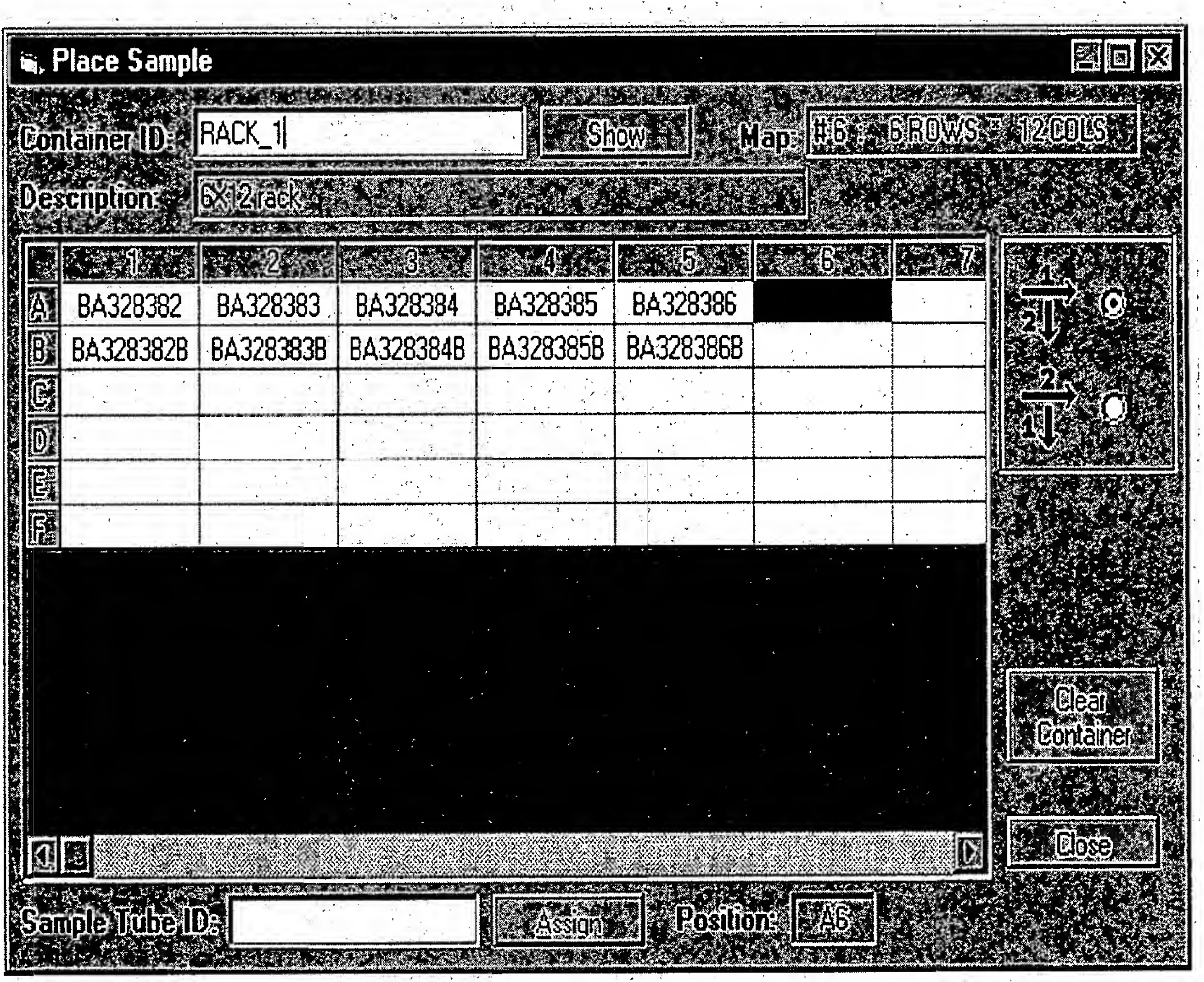
Created: DNALIMS 10/9/99 20:03

Modified:

Fig. 3

Sample Tracking

- Supports Multiple Container Classes
- Allows User Defined Container Geometries & Templates
- Maintains Sample & Container Location
- Permits Flexible Sample Loading & Rearrangement
- Tracks and Maintains Container & Sample Ownership



Container ID: RACK_1

Map: #6 : 6 ROWS * 12 COLS

Description: 6X12 rack

	1	2	3	4	5	6	7
A	BA328382	BA328383	BA328384	BA328385	BA328386		
B	BA328382B	BA328383B	BA328384B	BA328385B	BA328386B		
C							
D							
E							
F							

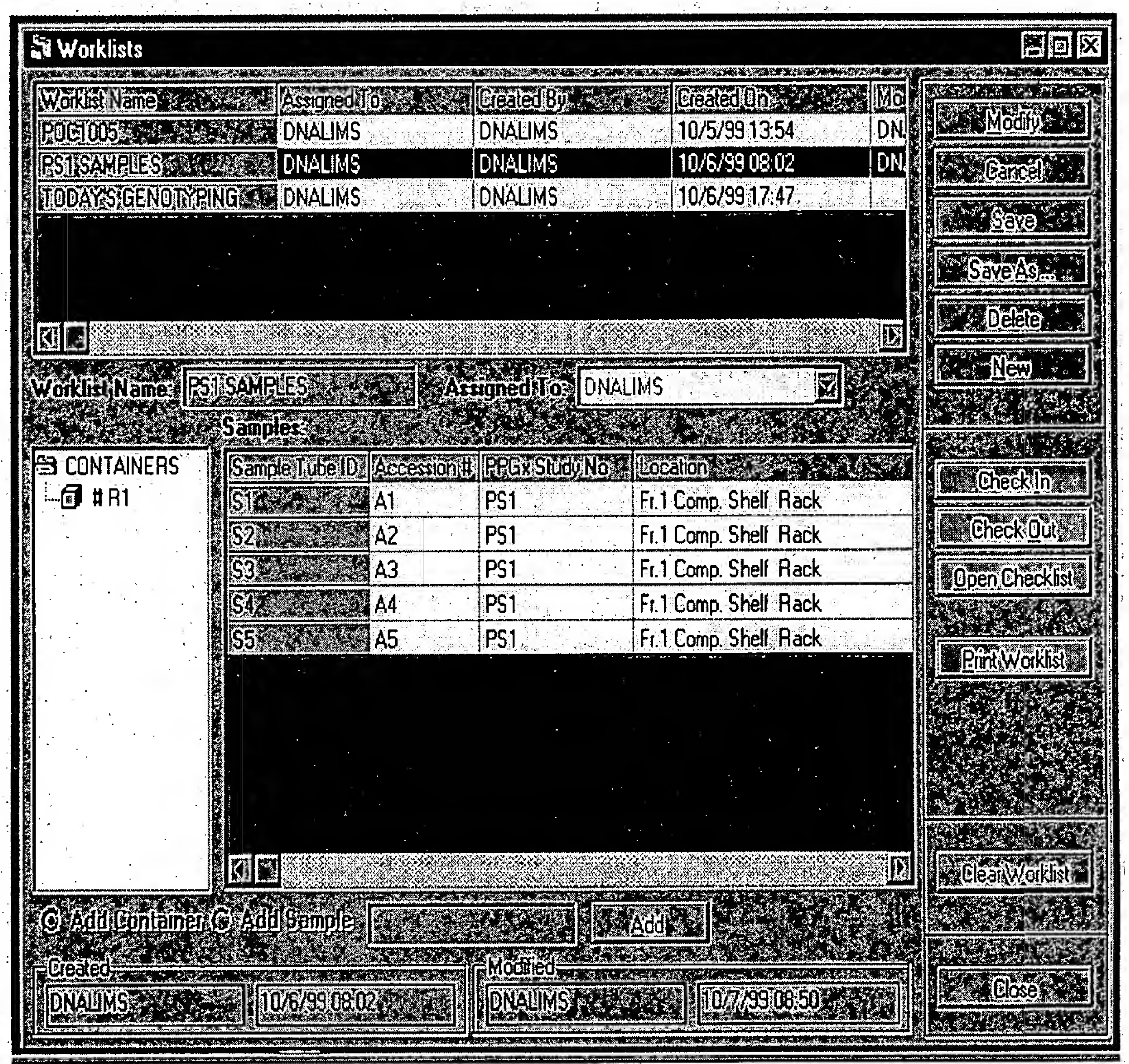
Sample Tube ID:

Position: A6

Fig. 4

Sample Worklists

- Named Sample Collections
- Assignable to Lab Scientists
- Groups Samples for Common Lab Operations
  - Location
  - Check-in/Check-out
  - Lab Procedures



Worklist Name	Assigned To	Created By	Created On	Mo
POC1005	DNALIMS	DNALIMS	10/5/99 13:54	DN
PS1 SAMPLES	DNALIMS	DNALIMS	10/6/99 08:02	DN
TODAY'S GENOTYPING	DNALIMS	DNALIMS	10/6/99 17:47	

Worklist Name: PS1 SAMPLES
Assigned To: DNALIMS

Samples:

CONTAINERS
R1

Sample Tube ID	Accession #	PPGx Study No	Location
S1	A1	PS1	Fr.1 Comp. Shelf Rack
S2	A2	PS1	Fr.1 Comp. Shelf Rack
S3	A3	PS1	Fr.1 Comp. Shelf Rack
S4	A4	PS1	Fr.1 Comp. Shelf Rack
S5	A5	PS1	Fr.1 Comp. Shelf Rack

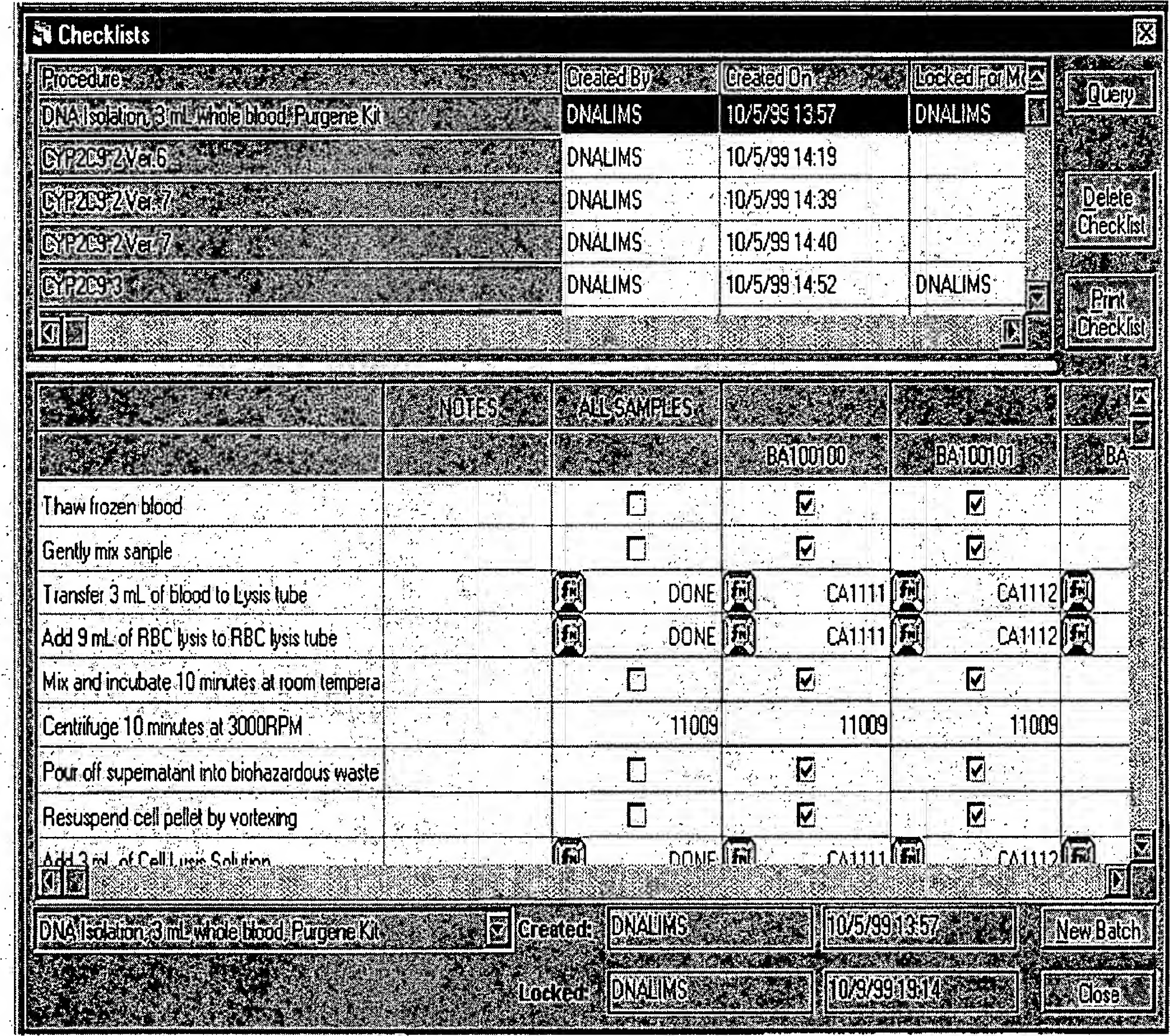
● Add Container ○ Add Sample

Created: DNALIMS 10/6/99 08:02
Modified: DNALIMS 10/7/99 08:50

Fig. 5

Electronic Procedure Checklists

Automates Laboratory Process Tracking
- Supports Standard Operating Procedures
- Maintains Uniform Laboratory Processes
- Records Chain of Custody
- Tracks Repeat Operations



Procedure	Created By	Created On	Locked For M
DNA Isolation, 3 mL whole blood, Purgene Kit	DNALIMS	10/5/99 13:57	DNALIMS
CYP2C9*2 Ver.6	DNALIMS	10/5/99 14:19	
CYP2C9*2 Ver. 7	DNALIMS	10/5/99 14:39	
CYP2C9*2 Ver. 7	DNALIMS	10/5/99 14:40	
CYP2C9*3	DNALIMS	10/5/99 14:52	DNALIMS

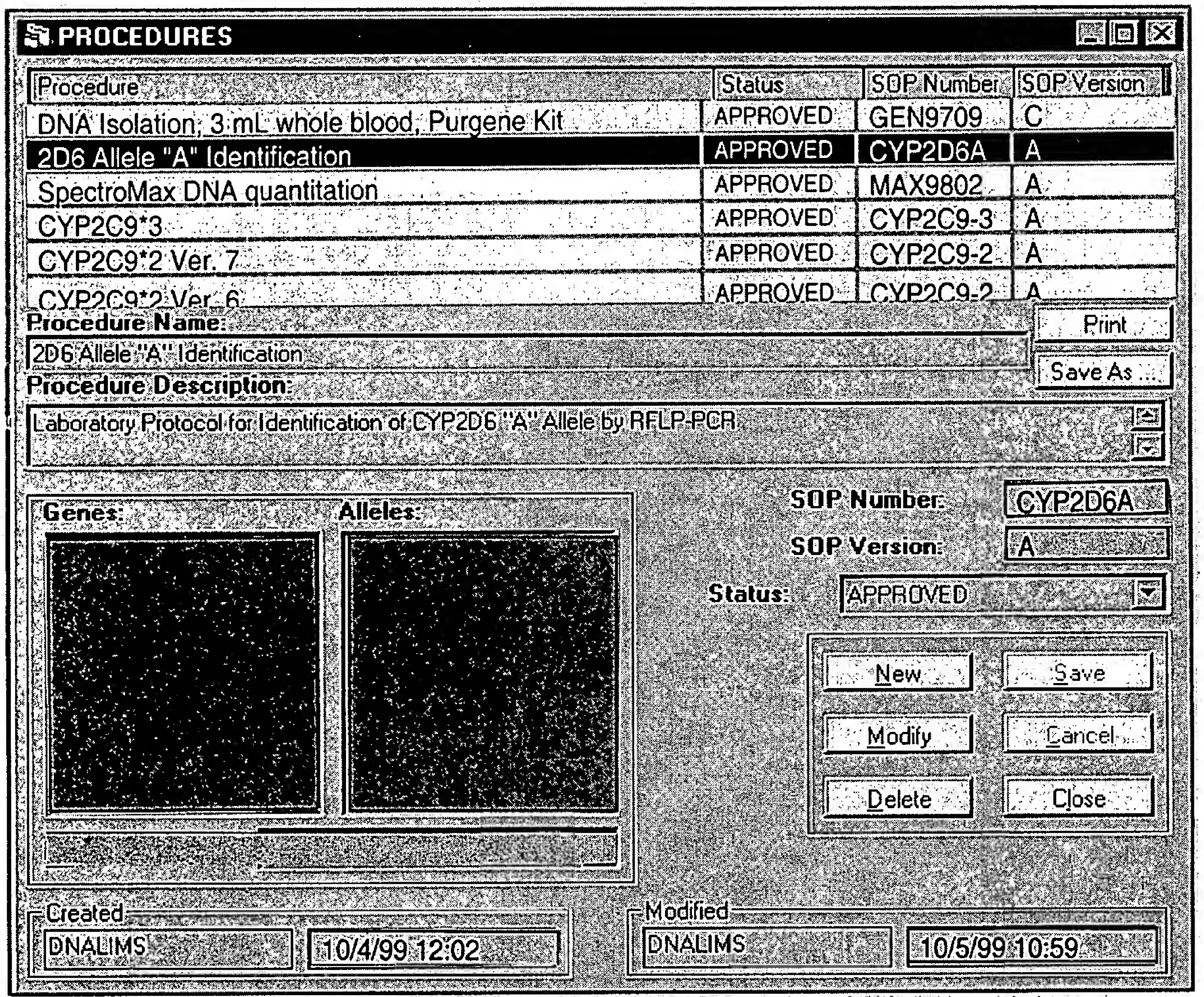
	NOTES	ALL SAMPLES			
			BA100100	BA100101	BA
Thaw frozen blood		☐	☑	☑	
Gently mix sample		☐	☑	☑	
Transfer 3 mL of blood to Lysis tube		DONE	CA1111	CA1112	
Add 9 mL of RBC lysis to RBC lysis tube		DONE	CA1111	CA1112	
Mix and incubate 10 minutes at room tempera		☐	☑	☑	
Centrifuge 10 minutes at 3000RPM		11009	11009	11009	
Pour off supernatant into biohazardous waste		☐	☑	☑	
Resuspend cell pellet by vortexing		☐	☑	☑	
Add 3 mL of Cell Lysis Solution		DONE	CA1111	CA1112	

DNA Isolation, 3 mL whole blood, Purgene Kit

Created: DNALIMS 10/5/99 13:57

Locked: DNALIMS 10/9/99 19:14

Fig. 6



Procedure	Status	SOP Number	SOP Version
DNA Isolation, 3 mL whole blood, Purgene Kit	APPROVED	GEN9709	C
2D6 Allele "A" Identification	APPROVED	CYP2D6A	A
SpectroMax DNA quantitation	APPROVED	MAX9802	A
CYP2C9*3	APPROVED	CYP2C9-3	A
CYP2C9*2 Ver. 7	APPROVED	CYP2C9-2	A
CYP2C9*2 Ver. 6	APPROVED	CYP2C9-2	A

Procedure Name: 2D6 Allele "A" Identification

Procedure Description: Laboratory Protocol for Identification of CYP2D6 "A" Allele by RFLP-PCR

Genes:

Alleles:

SOP Number: CYP2D6A

SOP Version: A

Status: APPROVED

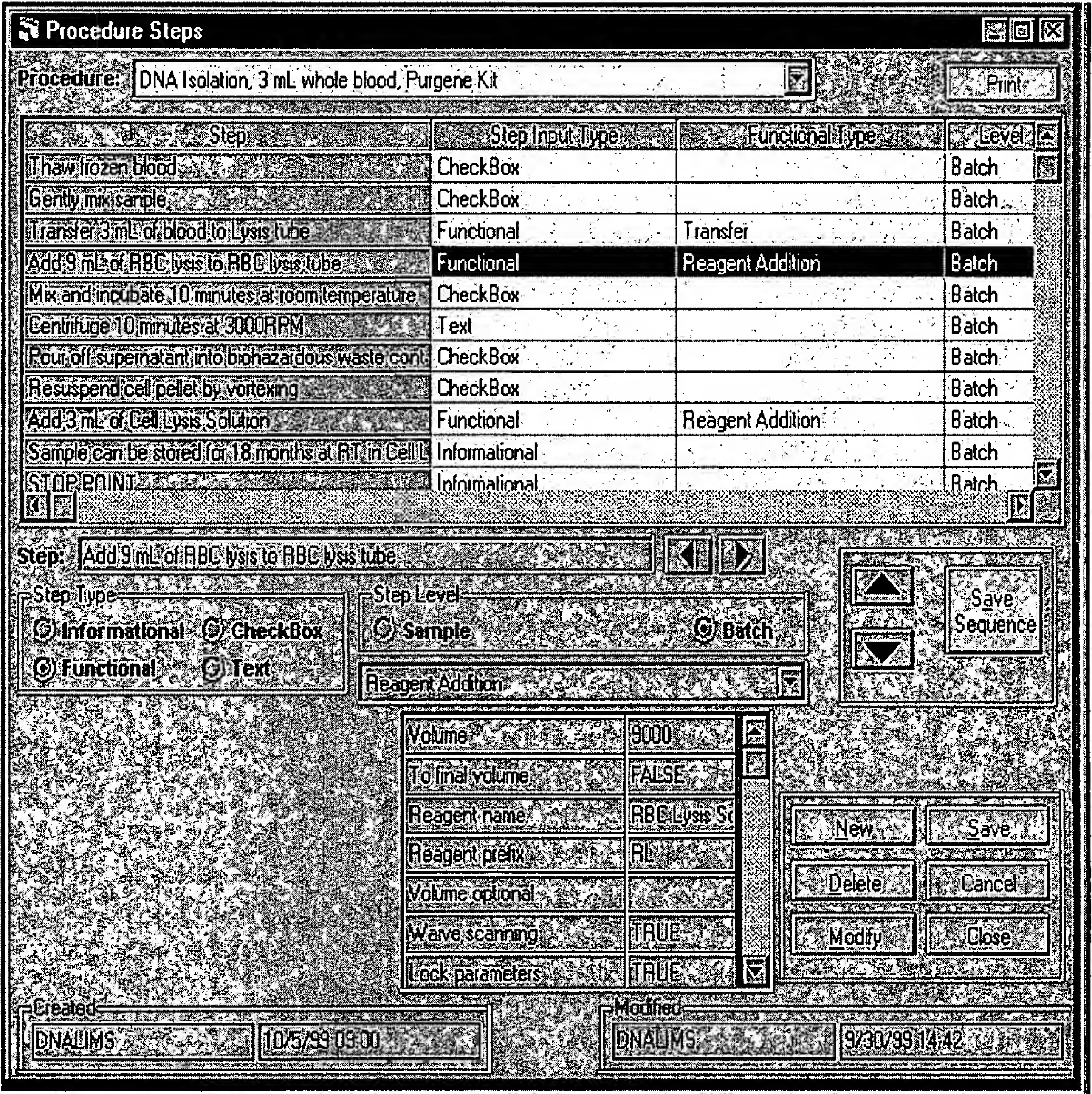
Created: DNALIMS 10/4/99 12:02

Modified: DNALIMS 10/5/99 10:59

Fig. 7

Procedure Steps

- A Single Step in a Lab Procedure
- Multiple Types:
  - Transfer
  - Dilution
  - Concentration Adjustment
  - Sample Preparation
- Highly Customizable
- Plug-in Architecture to Add New Types
- Interfaces to Automation



Procedure: DNA Isolation, 3 mL whole blood, Purgene Kit

Step	Step Input Type	Functional Type	Level
Thaw frozen blood	CheckBox		Batch
Gently mix sample	CheckBox		Batch
Transfer 3 mL of blood to Lysis tube	Functional	Transfer	Batch
Add 9 mL of RBC lysis to RBC lysis tube	Functional	Reagent Addition	Batch
Mix and incubate 10 minutes at room temperature	CheckBox		Batch
Centrifuge 10 minutes at 3000RPM	Text		Batch
Pour off supernatant into biohazardous waste cont	CheckBox		Batch
Resuspend cell pellet by vortexing	CheckBox		Batch
Add 3 mL of Cell Lysis Solution	Functional	Reagent Addition	Batch
Sample can be stored for 18 months at RT in Cell L	Informational		Batch
STOP POINT	Informational		Batch

Step: Add 9 mL of RBC lysis to RBC lysis tube

Step Type: ○ Informational ○ CheckBox ● Functional ○ Text

Step Level: ○ Sample ● Batch

Reagent Addition

Volume	9000
To final volume	FALSE
Reagent name	RBC Lysis Sc
Reagent prefix	RL
Volume optional	
Wave scanning	TRUE
Lock parameters	TRUE

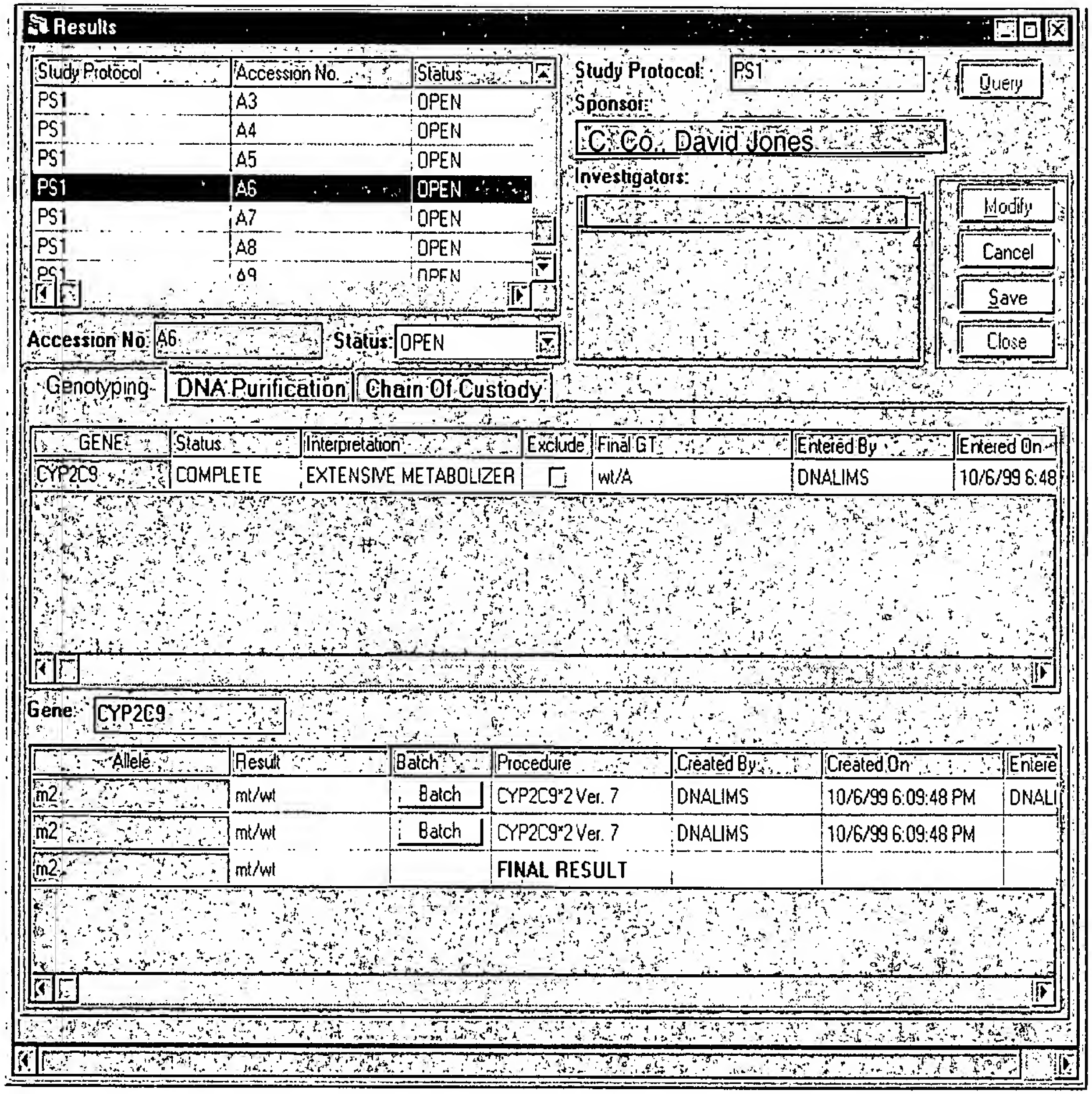
Created: DNALIMS 10/5/99 09:00

Modified: DNALIMS 9/30/99 14:42

Fig. 8

Genotype Results

- Accommodates Values for Multiple Genes, Alleles & Assays
- Provides Master Review by Accession Number
- Supports Acceptance & Final Approval by Study Director
- Imports Results Electronically or Manually



Study Protocol	Accession No.	Status
PS1	A3	OPEN
PS1	A4	OPEN
PS1	A5	OPEN
PS1	A6	OPEN
PS1	A7	OPEN
PS1	A8	OPEN
PS1	A9	OPEN

Study Protocol: PS1

Sponsor: C Co. David Jones

Investigators:

Accession No: A6 Status: OPEN

GENE	Status	Interpretation	Exclude	Final GT	Entered By	Entered On
CYP2C9	COMPLETE	EXTENSIVE METABOLIZER	☐	wt/A	DNALIMS	10/6/99 6:48

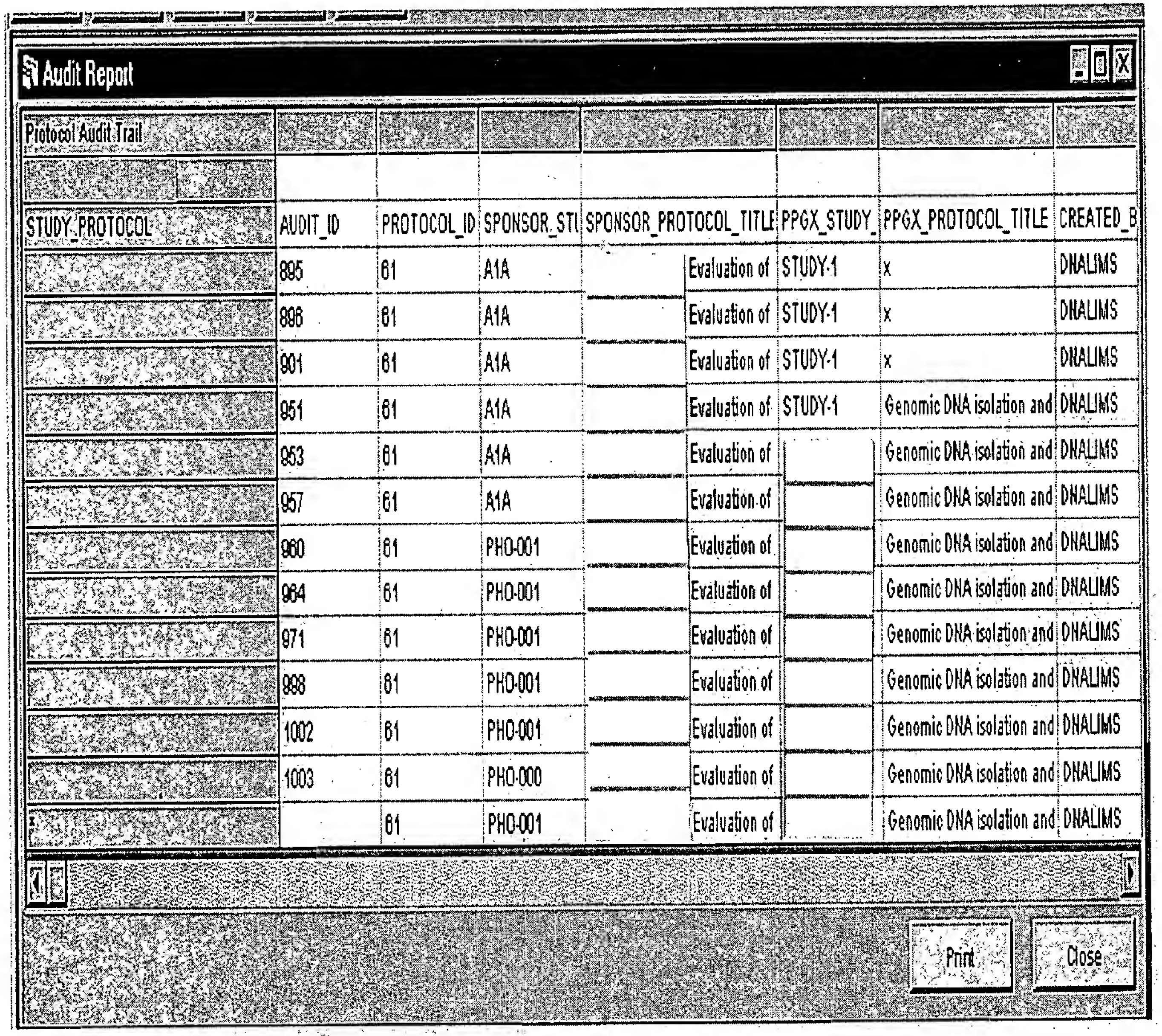
Gene: CYP2C9

Allele	Result	Batch	Procedure	Created By	Created On	Entere
m2	mt/wt	Batch	CYP2C9*2 Ver. 7	DNALIMS	10/6/99 6:09:48 PM	DNALI
m2	mt/wt	Batch	CYP2C9*2 Ver. 7	DNALIMS	10/6/99 6:09:48 PM	
m2	mt/wt		FINAL RESULT			

Fig. 9

Auditing

- Track Changes in Database
  - Study
  - Lab Procedures
  - Sample
  - Results
- Flexible Audit Reporting
- Chain of Custody by Accession



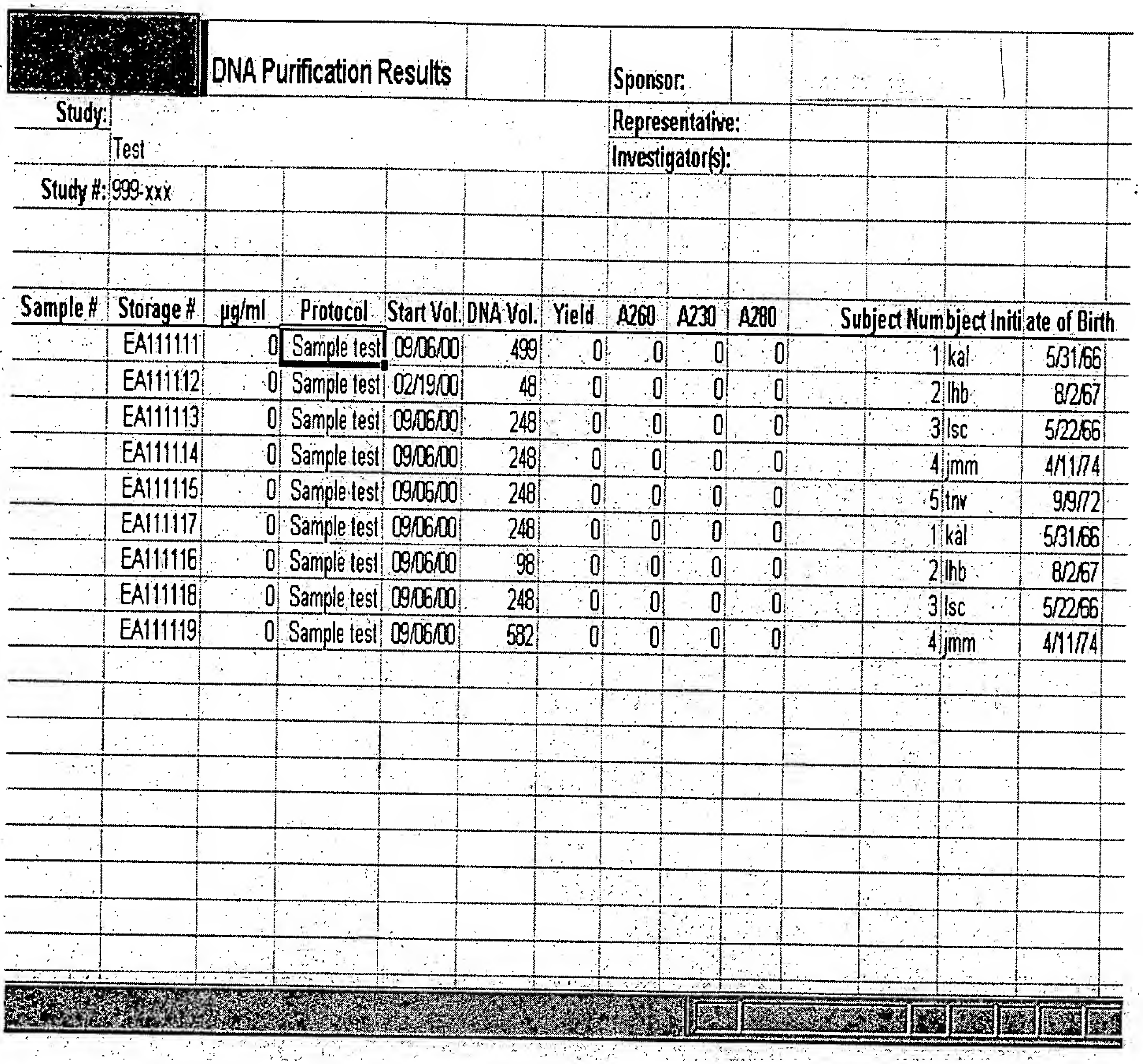
Protocol Audit Trail

STUDY_PROTOCOL	AUDIT_ID	PROTOCOL_ID	SPONSOR_STI	SPONSOR_PROTOCOL_TITLE	PPGX_STUDY_	PPGX_PROTOCOL_TITLE	CREATED_B
	895	61	A1A	Evaluation of	STUDY-1	x	DNALIMS
	898	61	A1A	Evaluation of	STUDY-1	x	DNALIMS
	901	61	A1A	Evaluation of	STUDY-1	x	DNALIMS
	951	61	A1A	Evaluation of	STUDY-1	Genomic DNA isolation and	DNALIMS
	953	61	A1A	Evaluation of		Genomic DNA isolation and	DNALIMS
	957	61	A1A	Evaluation of		Genomic DNA isolation and	DNALIMS
	960	61	PHO-001	Evaluation of		Genomic DNA isolation and	DNALIMS
	964	61	PHO-001	Evaluation of		Genomic DNA isolation and	DNALIMS
	971	61	PHO-001	Evaluation of		Genomic DNA isolation and	DNALIMS
	988	61	PHO-001	Evaluation of		Genomic DNA isolation and	DNALIMS
	1002	61	PHO-001	Evaluation of		Genomic DNA isolation and	DNALIMS
	1003	61	PHO-000	Evaluation of		Genomic DNA isolation and	DNALIMS
		61	PHO-001	Evaluation of		Genomic DNA isolation and	DNALIMS

Fig. 10

Reporting

- Multiple Report Types
  - Genotype Results
  - DNA Integrity
  - Purification Results
  - Sample Lists
  - Audit Trails
- Flexible Reporting Output Using Excel
- Customized Reporting Using 3rd Party Tools



DNA Purification Results

Study: Test

Study #: 999-xxx

Sponsor:

Representative:

Investigator(s):

Sample #	Storage #	µg/ml	Protocol	Start Vol.	DNA Vol.	Yield	A260	A230	A280	Subject Numb	ject Initi	ate of Birth
	EA111111	0	Sample test	09/06/00	499	0	0	0	0	1	kal	5/31/66
	EA111112	0	Sample test	02/19/00	48	0	0	0	0	2	lhb	8/2/67
	EA111113	0	Sample test	09/06/00	248	0	0	0	0	3	lsc	5/22/66
	EA111114	0	Sample test	09/06/00	248	0	0	0	0	4	jmm	4/11/74
	EA111115	0	Sample test	09/06/00	248	0	0	0	0	5	tnv	9/9/72
	EA111117	0	Sample test	09/06/00	248	0	0	0	0	1	kal	5/31/66
	EA111116	0	Sample test	09/06/00	98	0	0	0	0	2	lhb	8/2/67
	EA111118	0	Sample test	09/06/00	248	0	0	0	0	3	lsc	5/22/66
	EA111119	0	Sample test	09/06/00	582	0	0	0	0	4	jmm	4/11/74

Fig. 11